



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,589	12/04/2003	Matthew P. Carter	10000/218	8981
757	7590	12/07/2006	EXAMINER	
BRINKS HOFER GILSON & LIONE P.O. BOX 10395 CHICAGO, IL 60610			TYSON, MELANIE RUANO	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 12/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/728,589	Applicant(s) CARTER ET AL.	
	Examiner Melanie Tyson	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-23 and 33-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-32 and 36 is/are rejected.
- 7) ☒ Claim(s) 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/4/04 & 8/22/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election **without traverse** of Group I in the reply filed on 09 November 2006 is acknowledged. Claims 1-23 and 33-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. The requirement is made FINAL.

Claim Objections

2. Claim 25 is objected to because of the following informalities: claim 25 contains the limitations "the first distal portion" and "the second distal portion." There is insufficient antecedent basis for these limitations in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 24 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Eidenschink (Publication No. 2005/01922656 A1). Eidenschink discloses a method of placing first (22) and second (24) stents (second sentence of paragraph 36) into a

Art Unit: 3731

bifurcation using a stent delivery device (Figures 6A and 6B) comprising the steps of placing a first (26) and second (28) wire guide in an adjacent configuration, placing a first wire guide (26) into a main lumen (12) and a first branch lumen (14), placing a second wire guide (28) into a main lumen and a second branch lumen (16), and advancing first (38) and second (36) introducers over the first (26) and second (28) wire guides such that the first (38) and second (36) introducers are simultaneously positioned within the main lumen (12) and the first (14) and second (16) branch lumens, and such that the first distal portion is distal to the second distal portion (since they are situated away from each other; paragraph 41).

5. Claims 26, 27, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Dorros (Patent No. 5,720,735). Dorros discloses a method of placing stents within branch lumens and a main lumen comprising the steps of providing a first introducer (Figures 5 and 6, not labeled; arm in branch lumen 40) having a first stent (64), providing a second introducer (arm in branch lumen 42) adjacent to the first introducer having a second stent (66), placing a first (28) and second (30) wire guide into the main lumen (not labeled; ends at the apex of the "V" portion) and the first (40) and second (42) branch lumens, advancing the first and second introducers over the first (28) and second (30) wire guides such that the first and second introducers are simultaneously positioned within the main lumen and the first (40) and second (42) branch lumens, and deploying the first stent (64, Figure 9; column 6, lines 26-30 and 42-46). Figures 5 and 6 show the first and second introducers comprise proximal ends (tapered distal tips) and distal ends (portion extending away from the tapered tips), wherein the distal ends have

Art Unit: 3731

a diameter greater than the proximal ends and the proximal outer diameter is disposed adjacent to the second distal outer diameter (Figures 5 and 6; column 6, lines 26-30).

6. Claims 30 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Globerman (Publication No. 2006/0100694 A1). Globerman discloses a method of placing stents within branch lumens and a main lumen (Figures 2A-2F) comprising the steps of positioning the first (210) and second (220) stents within the first (103) and second (104) branches such that the distal portions extend at least partially within the first (103) and second (104) branch and the proximal portion extends at least partially within the main lumen (118), providing an open access to the second branch (104) as the first stent (210) is positioned, and deploying the first (130) and second (128) stents (see Figures 2A-F and paragraphs 111-122).

7. Claims 26, 28, 30, and 32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Carleton et al. (Patent No. 6,142,973). Carleton et al. discloses a method of placing stents within branch lumens and a main lumen (Figure 6) comprising the steps of providing a first introducer (Figure 5, 118) having a first stent (130), providing a second introducer (120) adjacent to the first introducer having a second stent (128), placing a first (119) and second (119) wire guide into the main lumen (118) and the first (not labeled) and second (not labeled) branch lumens, advancing first (118) and second introducers (120) over the first (119) and second (119) wire guides such that the first and second introducers are simultaneously positioned within the main lumen (118) and the first (40) and second (42) lumens and the distal portion of the first (130) and second (128) stents extend at

Art Unit: 3731

least partially within the first branch and the proximal portion extends at least partially within the main lumen (118), and simultaneously deploying the first (130) and second (128) stents (column 6, lines 38-43; column 1, line 41; column 6, lines 62-63; column 7, lines 2-18). Although the method shown in Figure 6 illustrates deploying a single stent, it is inherent that the method disclosed is also used for deploying the two stents shown in Figure 5. However, in the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the method disclosed to deploy the two stents shown in Figure 5, in order facilitate the treatment of lesions in branched or bifurcated arteries (column 1, lines 40-67).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Globerman in view of Mikus et al. (Publication No. 2002/0035391 A1). Globerman

Art Unit: 3731

discloses a method as described above, however, does not disclose the step of providing an endoscope having a working channel. Mikus et al. disclose a stent delivery system (Figure 2), wherein an endoscope (19) with a working channel (28) is provided. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an endoscope with a working channel in the method of Globerman as taught by Mikus et al. in order to be able to locate the stent placement through direct vision (paragraph 6).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 9:00 a.m. - 6:30 p.m., alternate Fridays 9:00 a.m. - 5:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Art Unit: 3731

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson *MT*
November 28, 2006

[Signature]
ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

12/3/06